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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26-IV-2007
C(2007) 1936

NOT FOR PUBLICATION

COMMISSION DECISION

of 26-IV-2007

amending the marketing authorisation for "Lysodren - Mitotane", a medicinal product for human use, granted by Decision C(2004)1765

(ONLY THE FRENCH TEXT IS AUTHENTIC)

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amending the marketing authorisation for "Lysodren - Mitotane", a medicinal product for human use, granted by Decision C(2004)1765

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93², and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application(s) submitted by Laboratoire HRA Pharma on 23 January 2007 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 22 March 2007,

Whereas:

- (1) An examination of the major variation type II to the terms of the marketing authorisation for the medicinal product "Lysodren - Mitotane", which is entered in the Community Register of Medicinal Products under number(s) EU/1/04/273/001 and the placing on the market of which was authorised by Decision C(2004)1765 of 28 April 2004, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the

¹ OJ L 136, 30.4.2004, p. 1, Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

² OJ L 159, 27.6.2003, p. 24.

European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use³.

- (2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2004)1765 accordingly.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)1765 is amended as follows:

- 1) Annex I is replaced by the text set out in Annex I to this Decision;
- 2) Annex II is replaced by the text set out in Annex II to this Decision;
- 3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Laboratoire HRA Pharma, 15, rue Béranger, 75003 Paris, France.

Done at Brussels, 26-IV-2007

For the Commission
Heinz ZOUREK
Director-General

³ OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1